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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,624	12/08/2000	David G. Lamphere	1611/122	2412
2101	7590	10/23/2003	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			SORKIN, DAVID L	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,624

Applicant(s)

LAMPHERE ET AL.

Examiner

David L. Sorkin

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. New claim 8 requires, "the rigid bottom surface further comprises a portion of the rigid wall". It is considered that this limitation is not supported by the specification, in combination with the limitations of claim 1 from which claim 8 depends. The "rigid bottom surface" is required to be "substantially flat" and comprise "a perforate interior wall". Regarding the embodiment(s) of Figs. 1, 2, 5 and 6 the flat rigid bottom surface is formed entirely by the perforate wall 40, and does not comprise the rigid wall 10. Regarding the embodiment of Figs. 3 and 4, the specification explicitly states on page 4, lines 6-8 that this embodiment includes alternative parts "instead" of a perforate wall. Furthermore, even if one considered that wall 237 is a "perforate" wall contrary to page 4, lines 6-8, it does not have a "flat" bottom surface, but instead has a grooved bottom surface. Also, there is no disclosure of wall 237 forming a "flat" surface together with the rigid wall 10.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Headley et al. (US 5,885,239). Regard claim 1, Headley ('239) discloses a fluid processing disposable set (see col. 7, lines 56-57, "disposable processing set") comprising a fluid port (83); a variable-volume chamber in fluid communication with the fluid port, the chamber defined by a rigid wall (10) (see col. 7, lines 41-43, "rigid boundary wall") and an elastic wall (31) (see col. 7, lines 37-40, "diaphragm 31 is preferably made of an elastic, stretchable and resilient material"); and a rigid bottom surface (the bottom surface of plate 40) limiting, at least in part, the upward movement of the elastic wall and comprising a perforate interior wall (plate 40) located within the chamber, the rigid bottom surface being substantially flat; the elastic wall formed by a convoluted diaphragm (31) (see Fig. 12; note that applicant admits on page 6 of paper No. 16 that Fig. 12 of the reference discloses a convoluted diaphragm) with a region of convolution, the region substantially overlying the rigid bottom surface when in an unstretched state (See Figs. 11-13; col. 16, lines 34-55). Regarding claim 2, the set of Headley ('239) further comprises a rotary seal (48), the rotary seal coupled to the chamber (see Fig. 11). Regarding claim 4, the convoluted diaphragm has at least one fold (see Fig. 12 and applicant's admission on page 6 of paper No. 16 regarding Fig.

12). Regarding claim 5, the convoluted shaped diaphragm (31) has a plurality of folds (at least one on the outer periphery and at least one nearer the center which is discussed by applicant on page 6 of paper No. 16) the folds located symmetrically about an axis (see Fig. 12). Regarding claim 8, to the extent applicant intends claim 8 to read upon the embodiment of instant Figs. 3 and 4, these figures are identical to Figs. 41 and 42.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Headley et al. (US 5,885,239) in view of Lord et al. (US 1,885,457). Headley ('239) discloses a fluid processing disposable set (see col. 7, lines 56-57, "disposable processing set") comprising a fluid port (13/83) and a variable volume chamber in communication with the fluid port, the chamber defined by a rigid wall (10) (see col. 7, lines 41-43, "rigid boundary wall 10") and an elastic wall formed by a diaphragm (31) (see col. 7, lines 37-40, "diaphragm 31 is preferably made of an elastic, stretchable and resilient material"), the elastic wall sealed only at a mounting position on the rigid wall (see col. 7, lines 35-38, "sealed to a rigid, imperforate boundary wall 10 by an O-ring or other means"); a rotary seal (48) coupled to the fluid port (see Fig. 2), the rotary seal fluidly coupled to the chamber, wherein the diaphragm is essentially planar in an

unstretched position (see Figs. 2-4). Headley ('239) fails to disclose the diaphragm being "shaped" such that it has varying in thickness outside the immediate vicinity of the mounting position. Lord ('457) teaches a diaphragm (7) which is "shaped" such that it has varying in thickness outside the immediate vicinity of the mounting position (as required by instant claim 6) and the thickness is constant at locations equidistant from an axis (as required by instant claim 7) (see Figs. 1 and 2, page 1, lines 47-52; page 2, lines 3-29 and 41-57). It is considered that it would have been obvious to one of ordinary skill in the art to have varied the thickness of the diaphragm of Headley ('239) in the manner taught by Lord ('457), because Lord ('457) explains that such a varying of thickness provides the benefit of "surer union" between the diaphragm and other parts, while still allowing flexibility where needed (see page 1, lines 47-52).

Response to Arguments

7. Applicant argues regarding the section 102(b) rejection as anticipated by Headley ('239), that Headley ('239) does not show "overlap between a substantially flat, rigid bottom surface, having a perforate wall portion, and a region of convolution of an elastic diaphragm". However, as best seen in Fig. 11, Headley ('239) discloses exactly such a structure. The substantially flat rigid bottom surface of perforate wall portion (40) is overlapped by a convoluted region, for example at a radially inner portion of 40.

8. Regarding the section 103(a) rejection as obvious over Headley ('239) in view of Lord ('457), applicant argues that the secondary reference (Lord) does not disclose all the claimed limitations. Particularly, applicant argues that the secondary reference does not disclose "the elastic wall sealed only at a mounting position". However, the

secondary reference is not relied upon for teaching such a limitation, because the primary reference, Headley ('239), discloses this limitation. Obviously, both references are not each required to disclose every limitation.

Conclusion

9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

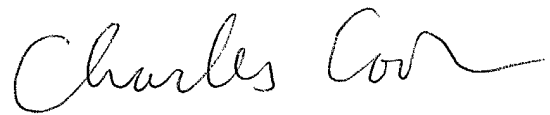
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin



CHARLES E. COOLEY
PRIMARY EXAMINER